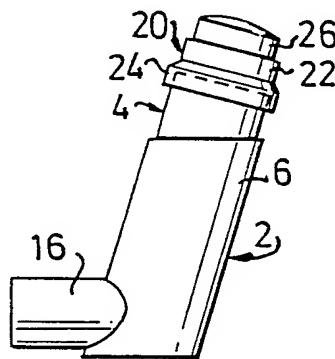




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61M 11/08, 15/00, A61J 7/00		A1	(11) International Publication Number: WO 86/ 02275 (43) International Publication Date: 24 April 1986 (24.04.86)
(21) International Application Number: PCT/SE85/00385 (22) International Filing Date: 8 October 1985 (08.10.85)			(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BG, BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (Utility model), DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.
(31) Priority Application Number: 4818/84 (32) Priority Date: 9 October 1984 (09.10.84)			
(33) Priority Country: DK			
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(54) Title: MEDICAL SPRAY DEVICE



(57) Abstract

An aerosol device comprising a pressurized aerosol container (4) having a dosing discharge valve (8) adapted to discharge a controlled quantity of fluid from the aerosol container (4) each time it is actuated. A counter (20) is arranged so as to be actuated by each actuation of the discharge valve (8), and said counter (20) being effective to give a visual indication when the container (4) is about to be exhausted.

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MEDICAL SPRAY DEVICEDESCRIPTION

The present invention relates to an aerosol device.

Most forms of aerosol device comprise a metal container and a discharge valve through which the fluid within the container may be discharged via a nozzle. The 5 discharge valve may give a continuous spray when they are actuated or they may give a dosed quantity. In either event, it is never clear to the user how much of the fluid remains within the container.

In many instances this will cause no real problems, 10 but it can be very unsatisfactory when the aerosol device is used for dispensing doses of a medicament. One particular type of such aerosol device is in the form of a medical mouth or throat spray device, which includes a holder for an aerosol container designed so as to discharge a 15 predetermined dose of a medicament each time the device is operated, the holder having a spray or atomizing nozzle through which doses are discharged. The aerosol container is provided with a depressable dosing valve having a discharge tube and is mounted or mountable in the holder 20 with this discharge tube received in the recess connected to the atomizer nozzle. The container is inserted and held in an outwardly open guide portion of the holder, such that the container is pressed downwardly in the guide portion, e.g. by applying thumb pressure on the base of the container, so 25 that the discharge nozzle is forced towards the interior of the container thereby discharging the dose of spray.

Devices of this type are used, for example, for dosed supply for the respiratory passages of patients having asthma or other respiratory diseases and they are used and 30 operated by the patients themselves. For the patients, it is often of the utmost importance that they should always have to hand an operative spray device, i.e. they should know when to procure a new device, or at least a new pressurized container, before an existing container has been

exhausted. These containers are usually metallic, to withstand the pressure and are thus not transparent, so that the patient cannot directly see how much medicament is left in the container. Theoretically this may be ascertained by weighing the container or by a buoyancy test,
5 whereby the container will float at a high level when it is about to be exhausted, but only relatively few patients are capable of carrying out such tests, e.g. determining whether a holiday period or even a weekend can be started
10 without previously obtaining a new container.

According to US-A-3505870, it has already been proposed to provide an aerosol container with a transparent window enabling the user to determine the remaining volume of liquid in the container, but this requires a
15 highly undesirable modification of the container itself.

The invention more specifically relates to an aerosol device comprising or consisting of a non-transparent aerosol container of the type operable to produce a predetermined dose by each actuation, and it is the purpose of
20 the invention to provide an aerosol device of this type, which will enable the user to easily determine when the container is about to be exhausted.

The invention is based on the recognition that this purpose is achievable by automatic counting of the consecutive actuations, provided it is known beforehand how many doses the aerosol container can produce. Basically, therefore, the invention resides in the combination of selecting an aerosol container holding a known number of doses and providing for an automatic counting of the actuations of the dosing discharge valve, such that the user
25 may somehow, all according to the manner in which the counting is effected, get warned when there is only a small number of doses left in the container.

However, in practice the invention is greatly assisted by an already established practice, according to which the aerosol containers of the relevant type are normally
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marked to hold a guaranteed number of doses, e.g. 200 or 400, and the capacity of a given aerosol container, therefore, will easily be relatable to an automatic counting of the actual doses discharged, without the user having 5 to know the exact number of doses actually present in the single container. The user may simply rely on the guaranteed number and observe the counter having counted up or down to or from this number corresponding to a remaining small number of the number of guaranteed doses.

10 Accordingly, based on this general concept, the invention is characterized by the features stated in the characterizing clause of claim 1.

It is readily admitted that it is well known in the art to automatically count the doses as discharged through 15 dosing valve means of various containers and bottles, primarily liquor bottles, but it will be appreciated that this is done for positively counting the discharged doses and not at all for telling the user when the bottle is about to be empty. Such dose counters have been in existence for many years without giving rise to any solution 20 of the problem here in question.

The invention as specifically relating to non-transparent aerosol containers and to a warning of such a container being "almost exhausted" could well, thus, make 25 use of some known dose counting system, e.g. including a direct operative connection between a discharge valve activating handle means and a counter unit, but the invention is still more specifically built on the recognition that such a direct operative connection as established 30 for each single aerosol container is avoidable due to the fact that the normal manner of actuating the discharge valve is to cause a displacement of the entire aerosol container relative the discharge tube thereof as held in said recess in a tube socket in the associated holder.

35 In a highly preferred embodiment of the invention, therefore, the counter unit is arranged so as to be actua-

ted by the very displacement of the aerosol container or - even preferably - by the force applied to the container for causing the actuation displacement thereof, whereby the single containers should not be provided with any special handle means for actuating the associated discharge valves. Thus, according to claim 2, the counter unit may be placed in connection with either the holder unit or the container so as to be operable by the displacement of the container or by the actuation pressing force on the container by each actuation thereof, without the discharge tube of the container having any kind of direct connection with the counter or with special actuator handle means.

The counter unit, therefore, may be arranged optionally in connection with the holder, so as to count each axial displacement of the container or each actuation pressure thereon as represented by the pressure of the discharge tube against said tube socket.

However, in a preferred embodiment of the invention the counting is effected based on the device normally being actuated by a finger pressure against the exposed bottom portion of the container, whereby the counter unit may comprise an actuation member located on the outside of the bottom portion of the container so as to be operable to effectively transfer an applied actuation pressure to said bottom portion and thereby even operate the counter unit.

Preferably, based on this concept, the actuation member is provided integrally with the counter unit, which, as a cap member, is mounted on the bottom end portion of the aerosol container. The counter unit as hereby being entirely separate from the holder will thus, on receiving an actuation pressure, both count the actuation and get displaced along with the container relative the holder.

It will be appreciated that a container as provided with such a counter end cap member may constitute a refill

unit to be placed in the holder upon the emptying of the preceding container. The invention, therefore, also comprises such a refill container unit, which can be used without any kind of adaptation for the present purpose.

5 The counter unit of the container unit may be preset in accordance with the guaranteed number of doses of the specific container.

The counter unit or member as placed on the bottom end of the container may well be disintegral with the container or sold as a separate unit, e.g. even for use as an interchangeable end cap member on several consecutively used standard containers, and the invention, therefore, even comprises such a separate counter unit.

10 The counter unit, generally, may operate according to any suitable principle, e.g. so as to just cause a visible signal to be produced when the container is about to be exhausted. Preferably, however, the counter should be an ordinary digital counter steadily displaying its respective counter stages, whereby the counter will enable 15 the patient to follow and control his treatment, insofar as the counter will make it possible to register the number 20 of doses which the patient inhales during a certain period of time.

In order that the invention may more readily be understood, the following description is given, merely by way 25 of example, reference being made to the accompanying drawings, in which:-

Figure 1 is a side elevation of one embodiment of aerosol device according to the invention;

30 Figure 2 is an enlarged, partly exploded view of the device of Figure 1, with parts being broken away and shown in section;

Figure 3 is an exploded side elevation of device 35 of Figures 1 and 2, with the actuation device being shown in section;

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Figure 4 is a view similar to the upper part of Figure 3, with the actuation device in position;

Figure 5 is an exploded enlarged perspective view of the counter and actuation member;

5 Figure 6 is a view similar to Figure 4, showing the actuation cap of the actuation member depressed; and

Figure 7 is a perspective view of a second embodiment of aerosol device according to the invention.

Referring first to Figures 1, 2 and 5, the medical spray device illustrated includes a conventional holder 2 and a conventional aerosol container 4 therein. The holder 2 comprises a cylindrical main portion 6, in which the container 4 is received by simply inserting it in an inverted position, whereby a dosing discharge valve having a discharge tube 8 is received in a recess 10. This is formed in an upstanding portion of a bottom wall 12 of the main portion 6. Connected to the recess 10 is a discharge spray nozzle 14, which is surrounded by a laterally extending spout 16. The neck of the container 4 includes the dosing discharge valve, which is actuatable for the delivery of a controlled predetermined quantity of fluid from the aerosol container 4, when the container is depressed downwardly to cause the discharge tube 8 to be moved towards the interior of the container. The discharge tube is resiliently biased, such that all that is necessary is to press the container 4 downwardly in the main portion 6 by finger pressure on the base of the container, whereby the released medicinal dose is discharged via the recess 10 through the nozzle 14 and the spout 16. Only one dose will be produced, irrespective of how long the user holds the container down. When the finger pressure is released, the container will return to its initial position under the action of the spring bias of the discharge tube 8, without producing any further discharge of medicine.

35 Adjacent the base of the container 4, which is directed upwardly, a counter 20 is provided, this including

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a holding portion 22 having a lower skirt 24, which engages the circumference of the base portion of the container 4, and an upper actuation cap 26 formed of transparent material. Inside the counter 20 is arranged a counting 5 train which is visible through a lens shaped top 28 of the actuation cap 26. The spray device can be operable by applying finger pressure onto the lens shaped top 28 of the counter, rather than directly on the exposed face of the container. During each actuation, the counter 20 will 10 transfer the required pressure to the container and, at the same time, effect a counting of the actuation, so as to display through the lens shaped top 28 the number of operations or dosages that have been effected since the container 4 and its associated counter were used for the 15 first time. Alternatively, and preferably, the counter unit, when associated with the container or the entire spray device initially, may be designed and adjusted so as to count down the number of actuations from the known number of dosages of the original container.

20 The counter 20 may be designed according to any known counting principle, but need not necessarily be a digital displaying counter, insofar as it achieves the desired result of a physical indication as to the state of the container. This can be marked, e.g., by a red marker coming 25 up into the lens shaped top 28, when there is a predetermined small number of doses remaining in the container.

However, in a preferred construction of the counter, an ordinary mechanical step counter with the required number 30 of digital wheels is provided. This enables the counter to be usable for therapeutic control during the entire lifetime of the container.

The construction of counter shown in Figures 3 to 6 comprises the holding portion 22 and the actuation cap 26, 35 the latter being formed as a short cylinder having its top end providing the lens shaped top 28 and its lower end being

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provided with an outwardly projecting chamfered flange 30. Inside the actuation cap 26 is arranged a main shaft 32 secured between opposed wall portions of the actuation cap, and a triple wheel digital wheel counter 34. On a second 5 shaft 36 is arranged, but not shown, two transfer wheels forming part of a counter of a well known type. The counter wheels are mounted between two end plates 38,40 which are supported, along their relative edges, against the inside of the actuation cap.

10 The end plate 40 is extended downwardly and is adapted for vertical reciprocation by having a vertical slot 42, through which the shaft 32 projects. At its lower left side (Figure 5) the end plate has a pawl 50, which is bent towards the first counter wheel for cooperation with 15 stepping knobs 52 thereon. Thus, the first counter wheel will count a step in response to each upward stroke of the end plate 40.

The holding portion 22 has a cylindrical main body 54, the top end of which has an inwardly projecting chamfered 20 flange 56, while at its lower end, the body 54 has an annular flange 58 just above the skirt 24. In the angle between the flange 58 and the skirt 24 is formed a stepped portion 60.

Between the actuation cap 26 and the holding portion 25 22 is placed an annular undulating spring 62, which acts between the top side of the annular flange 58 and the annular bottom surface of the actuation cap 26.

The parts 22, 26 and 62 are assembled simply by being pressed together, so that the lower outwardly projecting 30 chamfered flange 30 of the actuation cap 26 will snap under the inwardly projecting chamfered flange 56 of the holding portion 22, thus preventing subsequent separation of these parts. When they are fully pressed together, the spring 62 will become compressed and the end plate 40 is displaced 35 upwardly by contact between its lower flaps 46 and the top side of the annular flange 58. However, the end plate 40 moves against the top portion of the actuation cap 26 so as

to be forced down during the last phase of the pressing together of the parts. As a result, due to the shape and position of the flaps 46, which flaps are provided with downwardly converging outer edges 48, these flaps will 5 become forced below the annular flange 58 and will snap out underneath the flange, such that the edge portion of the flange will be received in notches 44, whereafter the end plates 40 will be vertically locked to the flange 58. When the actuation cap is released, the spring 62 will 10 push the actuation cap upwardly until it engages in the flange 56, but the end plate 40 does not participate in this, i.e. it will now be moved so as to prepare the counter for actuation by subsequent pressure on the actuation cap.

15 The assembled counter is placed on the base of the container 4, whereby the annular shoulder 60 will provide a free space accommodating the flaps 46 between the end surface of the container base and the underside of the flange 58. Thus, the flaps 46 are not clamped, and it will 20 be possible, therefore, to rotate the actuation cap on the holding portion 22, whereby the user may select any convenient rotational position for the digital counter.

25 The spring 62 is slightly weaker than, or as strong as, the spring which is provided to bias the discharge nozzle 8 of the container 4.

30 The operation of the counter will be clear from the foregoing. When the actuation cap 26 is pressed down to the extent that the container delivers a dose (Figure 6), the actuation cap will have been displaced relative to the end plate 40, whereby the counter is actuated and the subsequent release of the button (Figure 5) will cause the counter to become prepared for a subsequent actuation.

35 Figure 7 shows a modified spray device, in which the container holder, here designated 64, is provided with a counter unit comprising a counter wheel 66. In a manner (not shown) but readily understandable to a man skilled in the art, the counter can have an internal actuation member,

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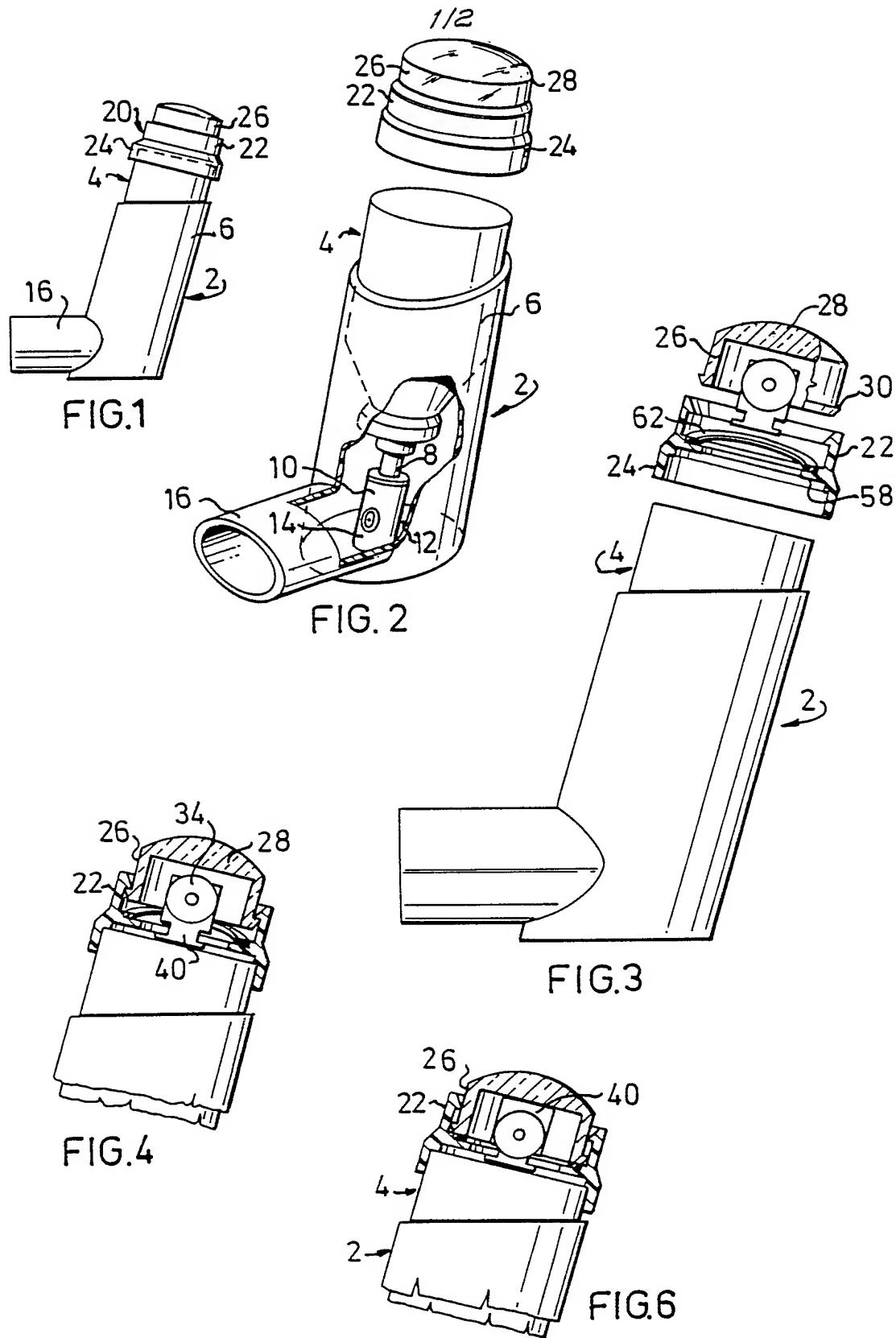
which is engaged by the neck portion of the container 4, so that depression thereof will cause the counter wheel to rotate one step.

CLAIMS:

1. An aerosol device comprising or consisting of a non-transparent aerosol container having a dosage discharge valve adapted to discharge a controlled quantity of fluid from the container each time it is actuated,
5 characterized in that the aerosol container is of the type containing a specified minimum number of doses and that the device comprises a counter arranged so as to be activated by each actuation of the discharge valve, the counter being effective to give a visual indication when
10 the container is about to have discharged the specified minimum of doses.
2. An aerosol device according to claim 1 and comprising a holder for the aerosol container, the holder having a recess for engaging a spring loaded discharge tube of the
15 dosing discharge valve of the container and a spray or atomizing nozzle connected to said recess, whereby, when said container is pushed to be displaced inwardly in said holder the discharge tube is depressed towards the interior of the container to hereby actuate the dosing discharge
20 valve, characterized in that the counter is arranged so as to be activated by each operative displacement of the container or by the pushing force applied to the container for effecting each operative displacement.
3. An aerosol device according to claim 2, characterized
25 in that the counter comprises an actuation member located at the outside of the end portion of the container opposite to said discharge tube, said actuation member being operable to transfer an applied actuation pressure to said container end portion and to hereby also activate the counter.
- 30 4. An aerosol device according to claim 3, characterized in that the counter is a counter unit directly associated with said actuation member and placed between said end portion of the container and said actuation member.

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5. An aerosol container for use in an aerosol device according to claim 4, provided at one end with a resiliently depressable discharge tube associated with a dosage discharge valve of or in the container, characterized in that
- 5 at the opposite end of the container there is arranged a counter unit comprising an outermost actuation member for receiving an actuation pressure towards the container, said counter unit being designed so as to count and display its counting for each consecutive application of an
- 10 actuation pressure against the container.
6. An aerosol container according to claim 5, characterized in that the counter is a conventional multiple digital wheel counter and that the actuation member includes a transparent lens portion to enlarge the display of the
- 15 counter.
7. An auxiliary unit for use on an end portion of an aerosol container according to claim 5, characterized in that it consists of a counter unit comprising a holding portion adapted to be fastenable to the base end portion
- 20 of the container and an actuation cap operable to receive an actuation pressure towards said container base end portion so as to transfer the actuation pressure to the container and additionally count the associated consecutive actuations of the dosage discharge valve of the container.
- 25 8. An auxiliary unit according to claim 7, characterized in that the counter is a conventional multiple digital wheel counter, which is housed within a casing as constituted by said holding portion and said actuation cap portion, these portions being mutually displaceable to enable an activation
- 30 of the counter.



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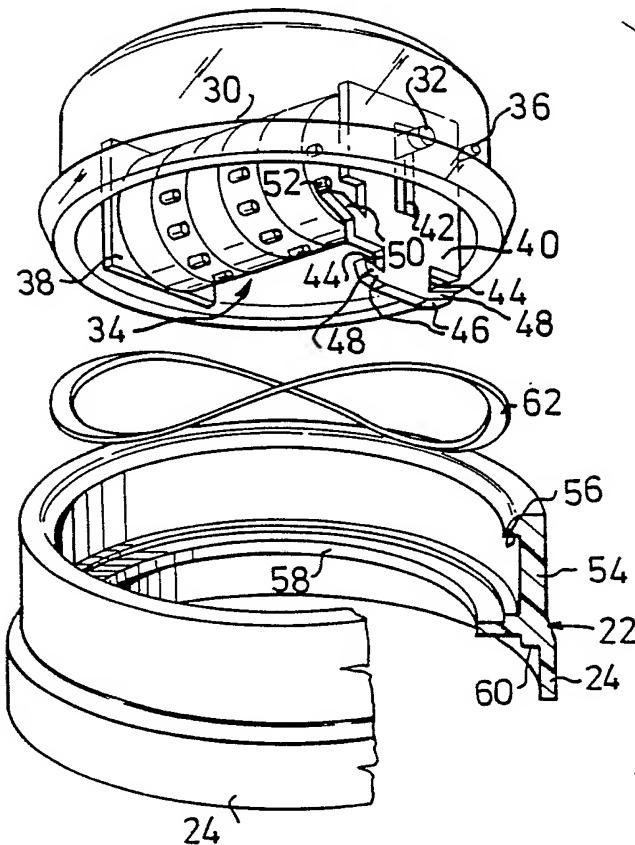


FIG. 5

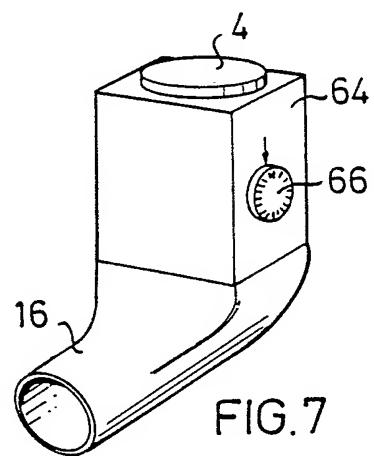


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No

PCT/SE85/00385

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 M 11/08, 15/00, A 61 J 7/00

II. FIELDS SEARCHED

Minimum Documentation Searched ?

Classification System	Classification Symbols
IPC 4	A 61 M 11-15, 25; G 01 F 23; B 67 D 5; B 05 B 11, 15;
Nat Cl	G 06 M 1/00, /02, /22, /24; A 61 J 7/00 30k:9, 11, 13/....

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched *

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT*

Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	GB, A, 1 317 315 (E.J. ELLIOTT) 16 May 1973	1, 2
X	EP, A, 0 028 929 (STERVIN AG.) 20 May 1981 & GB, 2063075 AT, 7264 NO, 146343	1, 2
A	EP, A, 0 114 617 (E. PFEIFFER GMBH & CO KG) 1 August 1984	1, 2
A	US, A, 3 419 187 (P.P. BAZARNIC) 31 December 1968	
A	US, A, 3 848 774 (SCHIMKE) 19 November 1974	
A	US, A, 4 034 757 (GLOVER) 12 July 1977	

* Special categories of cited documents: ¹⁰

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

1985-12-20

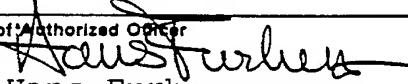
Date of Mailing of this International Search Report

1986-01-03

International Searching Authority

Swedish Patent Office

Signature of Authorized Officer


Hans Furhem

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FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET**II Fields Searched (cont).**

US Cl 73:293, 323, 330, 334;
116:118;
215:4, 100R;
220:82;
222:27, 36, 38, 204, 416;
235:94, 98, 64, 67, 103, 107, 133,
 134, 1;
128:173, 260, 185, 213, 265, 266;
604:58, 94

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. Claim numbers because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim numbers, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-6 concerning an aerosol device
Claims 7-8 concerning an auxiliary unit

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
 No protest accompanied the payment of additional search fees.